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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,327	02/24/2004	Paul J. Sheskey	63633	9686

109 7590 10/31/2007

THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION, P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
4173	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,327	SHESKEY ET AL.	
	Examiner	Art Unit	
	Caralynne Helm	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *4-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

Applicant's election of Group I in the reply filed on July 19, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The election is thereby made FINAL

Claims 9-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Objections

Claims 4-8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependant claim. See MPEP § 608.01(n). Accordingly, the claims 4-8 have not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al. (US Patent No. 7,223,421) in light of Lopez (US Patent No. 3,607,364), Doelker et al. (Drug Development and Industrial Pharmacy 1995, 21(6) pg 643-661),The USP Dictionary of U.S. Adopted Names and International Drug Names (USAN), and the Merck Index.

Lopez teaches a process of spray coating pharmaceutical solid forms (see column 1 lines 6-8). Lopez teaches that the process of coating solid forms by conventional means of dipping, pouring, or spraying often leads to unevenness in the coating layer (see column 1 lines 11-12 and 15-20). In addition, Lopez teaches that spray coating a liquid typically requires high pressures to appropriately atomize the coating medium and poses several challenges to uniform coating (see column 1 lines 46-75). The process taught by Lopez to circumvent the challenges of standard spray coating is amenable to nearly any type of coating medium and results in even and uniform coating, as well as shortened processing times (see column 2 lines 65-66 and 73-75). Lopez teaches the method of introducing air into a coating composition, which contains a surfactant and water, to produce foam that is then sprayed onto the pharmaceutical solid (see example and column 3 line 72-column 4 line 9; instant claims 1-2). Lopez does not teach a limitation on the particle size that is coated.

McTeigue et al. teach a method of producing a taste-masked pharmaceutical particle (see abstract). In particular, McTeigue et al. teach the importance of producing a continuous coating over the core of their particles to insure that no active ingredient is exposed (see paragraph 24 lines 1-4). McTeigue et al. go on to teach a listing of suitable surfactants to be included in the coating (see 20 lines 1-2 and 7-10). A particular example of the invention comprises a coating mixture with both water and polysorbate 80 (polymer/surfactant), where the polysorbate 80 constitutes 0.44% (as calculated by the examiner) of the liquid diluent and surfactant portion (see example 2; instant claims 1-2). The USP Dictionary of U.S. Adopted Names and International Drug Names (USAN) teaches that polysorbate 80 is a surfactant used in pharmaceuticals and, based upon its chemical structure as shown by the Merck Index, has a molecular weight of 1344 (instant claims 1-3). McTeigue et al. teach that the coating mixture is applied to ibuprofen powder and microcrystalline cellulose (Avicel® PH101) to produce particles

that are 323 microns in diameter (see paragraph 34 lines 1-2 and paragraph 35). The particle coating thickness is taught to range from 1 to 20 microns (see paragraph 25 lines 1-2). Doelker et al. teach that Avicel® PH101 particles are 50 microns in diameter (see page 645 paragraph 2 lines 4-5). McTeigue et al. do not explicitly teach the size of the ibuprofen powder grains. However, since the Avicel ® PH101 can occupy 50 microns while the coating occupies at least 2 microns within the 323 microns (diameter) particles, the ibuprofen must be less than approximately 271 microns in diameter (instant claims 1-2). Since the complete coverage of the ibuprofen containing particles is needed to produce a completely taste-masked result, one of ordinary skill in the art at the time the invention was made would have found it obvious to modify the invention of McTeigue et al. by using the foaming technique of Lopez to help ensure that complete and uniform coverage of the particles could be achieved. Therefore claims 1-3 are obvious over McTeigue et al. in light of Lopez, the Merck Index and the USP Dictionary of U.S. Adopted Names and International Drug Names.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,070,828. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim requires the same proportion of surfactant as well as the presence of drug in the fluid or solid used in the process as claim 1-2 in patent '828. Both the instant application and patent '868 teach a method of contacting particles with foam produced by combining a fluid with gas. In addition, the instant claim requires a range of molecular weights for the surfactant used as well as a range of particle sizes to be coated that each overlap with claims 1-2 of patent '828. Therefore, the claims are not patentably distinct.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Caralynne Helm
Examiner
Art Unit 4173

CH

10/28/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER